

Message Text

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PAGE 01 STATE 097227
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 ISO-00 OES-06 COME-00
EB-08 /052 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEWOIH:RFISCHER
ARA/MEX:GFALK(INFO)
EUR/NE:JPSHUMATE(INFO)
EUR/WE:MDURKEE(INFO)

-----300547Z 076045 /10

P 291951Z APR 77
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY MEXICO
AMEMBASSY LONDON
AMEMBASSY MADRID

UNCLAS STATE 097227

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, MX, UK, SP

SUBJECT: DEFECTIVE DIAGNOSTIC PRODUCT (RECALL T-098-7)

FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED: MALLINKRODT RES-O-MAT FE 59 DIAGNOSTIC
KIT - 12 TESTS FOR THE IN-VITRO DETERMINATION OF TOTAL IRON
BINDING CAPACITY (TIBC) AND UNSATURATED IRON BINDING
CAPACITY (UIBC). KIT CONTAINS 12 RESIN VIALS WITH 75 MG. OF
RESIN IN 1 ML. 0.6 CITRIC ACID, 24 RES-O-MAT FE 59
SOLUTION VIALS (EACH VIAL CONTAINS LESS THAN 0.20 MICROCURIE
FE 59 AS FERRIC AMMONIUM CITRATE IN 3 ML. ON DATE OF CALI-
BRATION), 24 RES-O-MAT (RESIN) STRIPS, 1 PAIR OF FORCEPS.
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PRODUCT IDENTIFICATION: PRODUCT NUMBER 260, LOT 78V.

MANUFACTURER/RECALLING FIRM:

MALLINKRODT NUCLEAR
2703 WAGNER PLACE

MARYLAND HEIGHTS, MISSOURI 63043

REASON FOR RECALL: FOLLOWING 21 COMPLAINTS RE: THIS LOT
(2/27/77)-3/21/77) REGARDING POOR FUNCTIONING OF KITS THE
FIRM ISSUED PRODUCT RECALL DUE TO RESIN BEADS APPEARING IN

THE RES-O-MAT FE 59 SOLUTION. ANY RESIN PRESENT WOULD
BIND THE FE 59 AND PREVENT PROPER FUNCTIONING OF TEST.

POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DE-
TERMINE IF CONSIGNEES HAVE RECEIVED URGENT DRUG RECALL
NOTICE DATED MARCH 22, 1977. ANY QUESTIONS CONSIGNEES
MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO FIRM.
CONTACT WILLIAM P. ROBB, MANAGER, QUALITY ASSURANCE,
TELEPHONE 314-291-0540. ALL KITS FROM THIS DEFECTIVE
LOT ARE TO BE RETURNED TO FIRM FOR CREDIT.

FOREIGN CONSIGNEES:

MALLINKRODT AUSTRALIAN DIVISION LTD.
P.O. BOX 313
MT. WAVERLY
VICTORIA
AUSTRALIA

LABORATORIOS DILUCION DE RADIOISOTAPES
INSTITUTO DE DILUCION
MIGUEL ANGEL DE QUEVIDO
5304 MEXICO D.F.
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MEXICO

PRODUCTION INEN
INSURGENTES SUR 1079
MEXICO 18 D.F.
MEXICO

MALLINKRODT LTD
BUILDING 521
5911 SOLENT ROAD
HEATHROW AIRPORT
LONDON
ENGLAND

MALLINKRODT IBERICA S.A.
JULIAN CAMARILLO 35
MADRID 17, SPAIN

CHRISTOPHER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 29-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE097227
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:PFF
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770151-0611
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977043/aaaaaceh.tel
Line Count: 117
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 6f278ea0-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 04-Feb-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2724797
Secure: OPEN
Status: NATIVE
Subject: DEFECTIVE DIAGNOSTIC PRODUCT (RECALL T-098-7) FDA ADVISES OF THE FOLLOWING PRODUCT RECALL: PRODUCT INVOLVED: MALLINKRODT RES-O-MAT FE 59 DIA
TAGS: OGEN, ETRD, EIND, TBIO, AS, MX, UK, SP, FDA
To: CANBERRA MEXICO MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/6f278ea0-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009